

REMARKS

Entry of the foregoing and prompt and favorable examination of the subject application are respectfully requested.

By the foregoing amendment, claims 1-6, 10, 12, 22-24 and 26-37 have been cancelled without prejudice or disclaimer, claims 7-9, 13-15 and 25 have been amended and new claims 38-89 have been added. Support for the amendments and new claims enclosed herewith can be found in the application as filed, and more specifically, as follows.

Claims 7, 13, 14 and 15 have been amended to refer to X¹ as an aromatic amino acid residue. This wording is supported in the application as filed, for example at page 3, line 23.

Claims 13 and 25 have been amended to refer to "treating or preventing systemic inflammatory response syndrome (SIRS)". Support for this amendment can be found throughout the application and, more particularly, at pages 8 to 9 which discuss SIRS and at page 11, lines 10 to 14, where it is indicated that the invention enables methods for preventing or treating a number of conditions including SIRS.

New claim 38, directed to the peptide of claim 7 wherein X¹ is phenyl alanine, is supported, for example, by Tables 2 and 3 in which a number of effective peptides are shown in which position X¹ is phenyl alanine.

Claims 39-46, which are dependent directly or indirectly on claim 13, parallel the possible peptide substitutions of former claims 2-6 and claim 7. These various possibilities

for the amino acids of the general peptide formula of claim 13 are also supported by Tables 2, 3 and 4.

Support for claims 47-48 can be found at page 9, lines 9-11, where it is indicated that SIRS can be associated with SIRS-induced hypotension and SIRS-induced shock.

Support for claim 49 can be found at page 2, lines 3-7, which indicate that sepsis syndrome or SIRS is associated with the conditions listed in the claim.

Claims 50-61, which are dependent directly or indirectly on claim 14, parallel claims 39-46 discussed above, and set out a number of possible substitutions in the general formula of the peptide.

Support for claim 62 can be found at page 7, lines 25-31, which indicate that anaphylactic reactions have a role in the etiology of, and therefore are associated with, asthma, rhinitis, urticaria and eczema.

Support for claim 63 can be found at page 7, lines 25-28, which indicate such anaphylactic reactions may occur in response to a food allergen.

Support for claim 64 can be found, for example, at page 4, lines 24-29 and at page 10, line 38, which indicates that the peptides of the invention may be used for the treatment of inflammation.

Claims 65-70, which are dependent directly or indirectly on claim 64, parallel claims 39-46 discussed above, and relate to possible peptide substitutions.

Support for claim 71 can be found at page 11, lines 2 to 4, which indicate that disorders which are ameliorated by down regulation of neutrophil function, in other words

disorders which are associated with inflammation, include rheumatic disorders, inflammatory bowel disease and post-ischemic lesions subsequent to stroke or cardiac infarct.

Support for claim 72 can be found, for example, at page 7, lines 16-19, which indicate that the peptides of the present invention modulate endotoxic reactions in mammals, and at page 10, lines 31 to 35, which indicate that these peptides may be used for treatment or prevention of endotoxic reactions.

Claims 73-78, which are dependent directly or indirectly on claim 72, parallel claims 39 to 46 discussed above and relate to possible peptide substitutions.

Support for claims 79 and 86 can be found, for example, at page 10, line 38, to page 11, line 2, which indicates that the peptides of the invention may be used for the treatment of any disorder ameliorated by down regulation of neutrophil function. Further support can be found in described examples of use of the peptides of the invention to reduce neutrophil function, for example inhibition of neutrophil migration (see page 10, lines 27 to 28 and Example 4) and neutrophil superoxide production (see page 10, lines 28 to 30 and Example 4 and 5).

Claims 80-85, which are dependent directly or indirectly on claim 79, parallel claims 39 to 46 discussed above and relate to possible peptide substitutions.

Support for claim 87 can be found at page 11, lines 1-4, where it is indicated that the peptides of the invention can be used to treat disorders ameliorated by down regulation of neutrophil function, including the diseases listed in the claim.

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Claims 88 and 89 correspond to original claims 19 and 20 which were deleted from the parent application in response to a Restriction Requirement.

Additionally, it is noted that the amendments to claims 7-9, 13-15 and 25 were not intended to narrow the scope of such claimed elements.

In the event that there are any questions relating to this application, it would be appreciated if the Examiner would telephone the undersigned attorney concerning such questions so that prosecution of this application may be expedited.

Respectfully submitted,

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Attachment to Preliminary Amendment dated February 28, 2001
Marked-up Claims 7, 9, 13-15 and 25

7. (Twice Amended) A peptide of the formula: $R^1-X^1-X^2-R^2$

wherein X^1 is [phenyl alanine] an aromatic amino acid residue;

X^2 is any amino acid residue; and

R^1 is NH_2- or an amino acid sequence $X^3-X^4-X^5$

wherein X^3 is an aliphatic amino acid residue having a side chain hydroxyl group and X^4 and X^5 are the same or different and are any amino acid residue and wherein R^2 is a sequence of 1 to 3 amino acid residues which are the same or different and are selected from the group consisting of glycine, sarcosine, azetidine, nipecotic acid and pipecotic acid.

9. (Twice Amended) The peptide of claim [2] 7 wherein at least one amino acid is a D-amino acid.

13. (Twice Amended) A method for treating or preventing [SIRS-induced hypotension] systemic inflammatory response syndrome (SIRS) in a mammal comprising administering to the mammal an effective amount of a peptide of the formula: $R^1 - X^1 - X^2 - R^2$

wherein X^1 is [phenyl alanine] an aromatic amino acid residue;

X^2 is any amino acid residue[,]; and

R^1 is NH_2- or an amino acid sequence $X^3 - X^4 - X^5$

wherein X^3 is an aliphatic amino acid residue having a side chain hydroxyl group and X^4 and X^5 are the same or different and are any amino acid residue and wherein R^2 is a sequence of 1 to 3 amino acid residues which are the same or different and are aliphatic amino acid residues or of an effective fragment or derivative of said peptide.

14. (Twice Amended) A method for treating or preventing anaphylactic hypotension in a mammal comprising administering to the mammal an effective amount of a peptide of the formula: $R^1 - X^1 - X^2 - R^2$

wherein X^1 is [phenyl alanine] an aromatic amino acid residue;

X^2 is any amino acid residue[,]; and

R^1 is NH_2- or an amino acid sequence $X^3 - X^4 - X^5$

wherein X^3 is an aliphatic amino acid residue having a side chain hydroxyl group and X^4 and X^5 are the same or different and are any amino acid residue and wherein R^2 is a sequence of 1 to 3 amino acid residues which are the same or different and are aliphatic amino acid residues or of an effective fragment or derivative of said peptide.

15. (Twice Amended) A method of reducing or preventing an anaphylactic reaction in a mammal comprising administering an effective amount of a peptide of the formula: $R^1 - X^1 - X^2 - R^2$

wherein X^1 is [phenyl alanine] an aromatic amino acid residue;

X² is any amino acid residue[,] : and

R¹ is NH₂- or an amino acid sequence X³ - X⁴ - X⁵

wherein X³ is an aliphatic amino acid residue having a side chain hydroxyl group and X⁴ and X⁵ are the same or different and are any amino acid residue and wherein R² is a sequence of 1 to 3 amino acid residues which are the same or different and are aliphatic amino acid residues or of an effective fragment or derivative of said peptide to the mammal.

25. (Amended) A method for treating or preventing [SIRS-induced hypotension] systemic inflammatory response syndrome (SIRS) in a mammal comprising administering to the mammal an effective amount of the peptide of claim [2] 11 or an effective fragment or derivative of said peptide.